K052716

NOV 16 2006

510(k) Summary
for
RAPIRUN *H. pylori* Antibody Detection Kit

1. SPONSOR

Otsuka Pharmaceutical Co., Ltd.
2-9 Kanda Tsukasa-cho, Chiyoda-ku
Tokyo 101-8535
Japan

Contact Person:
Japan: Kuniaki Natsume
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Telephone: 720-479-6449

Date Prepared: September 28, 2005

2. DEVICE NAME

Proprietary Name: RAPIRUN *H. pylori* Antibody Detection Kit

Common/Usual Name: Qualitative Immunoassay for *H. pylori*

Classification Name: *Campylobacter pylori*

3. PREDICATE DEVICES

- HM-CAP™ *H. pylori* Enzyme Immunoassay Test
  Enteric Products, Inc.
  K984544, K955085, K944159
- UBiT-IR300 Infrared Spectrophotometer
  Otsuka Pharmaceutical Co., Ltd.
  K013371
- Instant-View *H. pylori* Rapid Test
  Alfa Scientific Designs, Inc.
  K024360

4. DEVICE DESCRIPTION

The RAPIRUN *H. pylori* Antibody Detection Kit is an immunochromatographic method for the qualitative detection of anti-*H. pylori* antibodies in urine using a nitrocellulose membrane immobilized with proteins extracted from *H. pylori* as an antigen. The test device includes a sample window in which the test specimen is placed in a dropwise manner and an evaluation window in which a test line and a control line are visible. Colloidal gold-conjugated anti-human IgG (Fc) polyclonal antibody (goat) is present between the sample window and the evaluation window. The test line and the control line in the evaluation window are immobilized with *H. pylori*-extracted protein and with anti-human IgG polyclonal antibodies (goat), respectively.

When a urine specimen diluted with the sample diluent is added dropwise to the sample window, the IgG in the diluted sample reacts with the conjugated antibodies. Immunocomplexes are formed and flow into the nitrocellulose membrane. If anti-*H. pylori* IgG antibody complexes are present in these immunocomplexes, they react with the *H. pylori* antigen immobilizing on the test line and are captured producing a red band. On the other hand, immunocomplexes without anti-*H. pylori* IgG antibodies pass the test line and are captured by the anti-human IgG polyclonal antibodies (goat) immobilizing on the control line producing a red band. A test specimen is judged to be positive for anti-*H. pylori* antibodies if red colored bands appear in both the test zone and the control zone, or is judged to be negative for anti-*H. pylori* antibodies if a red colored band only appears in the control zone.

5. INTENDED USE

The RAPIRUN *H. pylori* Antibody Detection Kit is a rapid immunochromatographic assay intended for the qualitative detection of antibodies against *Helicobacter pylori* (*H. pylori*) in urine to aid in the diagnosis of *H. pylori* infection. The RAPIRUN Kit is suitable for use in both point-of-care and clinical laboratory settings.

6. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

The RAPIRUN Kit and the predicate devices cited above are all qualitative tests intended for use in the diagnosis of *H. pylori* infection. Like the RAPIRUN Kit, both the HM-CAP™ Test and the Instant-View Test detect IgG antibodies to *H. pylori* in the test sample. The UBiT-IR300 method measures changes in $^{13}CO_2$ content in breath CO_2 gas. The test samples vary among the devices. The RAPIRUN Kit is

used with urine samples, while the HM-CAP™ Test is used with serum or plasma, the UBiT-IR300 with breath, and the Instant-View Test with whole blood or serum.

Both the RAPIRUN Kit and the Instant-View Test are laminar flow chromatographic immunoassays with detection by visual inspection. The HM-CAP™ Test is an enzyme immunoassay with absorbance measured at 450 nm and the UBiT-IR300 is an infrared spectrophotometric method with detection by infrared absorption. The RAPIRUN Kit, UBiT-IR300, and Instant-View Test are primarily intended for use in point-of-care settings while the HM-CAP™ Test is for use in clinical laboratory settings.

The differences between the RAPIRUN Kit and the predicate devices do not impact the safety or effectiveness of the proposed RAPIRUN Kit for its intended use.

7. PERFORMANCE TESTING

7.1 Nonclinical Testing

A series of nonclinical studies was conducted to assess the performance of the RAPIRUN *H. pylori* Antibody Detection Kit. These studies evaluated reproducibility, interfering substances, cross-reactivity, high-dose hook effect, sample treatment and handling, and kit stability. The results of all studies demonstrated that the RAPIRUN Kit performed according to its specifications.

7.2 Clinical Testing

A clinical study was conducted to evaluate the performance of the RAPIRUN *H. pylori* Antibody Detection Kit for the qualitative detection of antibodies to *H. pylori* in urine. The multi-center, prospective study was designed to compare the RAPIRUN *H. pylori* Antibody Detection Kit for the qualitative detection of antibodies to *H. pylori* in urine to the HM-CAP™ *H. pylori* Enzyme Immunoassay Test for the detection of antibodies to *H. pylori* in serum and to the UBiT-IR300 Infrared Spectrophotometer method for measuring $^{13}CO_2$ enrichment in breath. Subjects were recruited at four Physician Office Laboratory (POL)/Point-of-Care (POC) settings. The total number of evaluable subjects was 188 across all participating sites.

The primary endpoint was the percent agreement of the RAPIRUN Kit results as compared to the HM-CAP™ EIA Test results. Both of these methods are tests for the qualitative detection of antibodies to *H. pylori*. The percent agreement for all subjects is as follows:

% Overall Agreement:	87.23%	[95% CI: (81.97, 91.39)]
% Positive Agreement:	84.71%	[95% CI: (75.82, 91.30)]
% Negative Agreement:	89.32%	[95% CI:(81.96, 94.31)]

A secondary endpoint was the percent agreement of the RAPIRUN *H. pylori* Antibody Detection Kit as compared to the UBiT-IR300 Infrared Spectrophotometer method for measurement of $^{13}CO_2$ enrichment in breath. The percent agreement for all subjects is as follows:

% Overall Agreement:	93.09%	[95% CI: (88.51, 96.27)]
% Positive Agreement:	86.46%	[95% CI: (78.53, 92.40)]
% Negative Agreement:	100.00%	[95% CI:(96.17, 100.00)]

For reference purposes, the results from the HM-CAP™ EIA Test also were compared to the results from the UBiT-IR300 Breath Test. The percent agreement for all subjects is as follows:

% Overall Agreement:	88.83%	[95% CI: (83.69, 92.65)]
% Positive Agreement:	83.33%	[95% CI: (75.02, 90.16)]
% Negative Agreement:	94.57%	[95% CI:(87.97, 97.83)]

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Otsuka Pharmaceutical Co., Ltd.
Cynthia A. Sinclair, RAC
Principal Consultant, Regulatory Services
Medical Device Consultants, Inc.
49 Plain Street
North Attleboro, MA 02760

NOV 16 2006

Re: k052716
Trade/Device Name: RAPIRUN *H. pylori* Antibody Detection Kit
Regulation Number: 21 CFR 866.3110
Regulation Name: Campylobacter Fetus Serological Reagents
Regulatory Class: Class I
Product Code: LYR
Dated: October 3, 2006
Received: October 5, 2006

Dear Ms. Sinclair:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

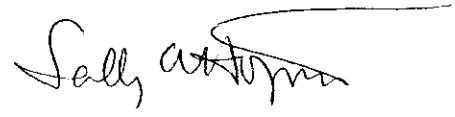
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240)276-0450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,



Sally A. Hojvat, M.Sc., Ph.D.
Director
Division of Microbiology Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: RAPIRUN *H. pylori* Antibody Detection Kit

Indications for Use:

The RAPIRUN *H. pylori* Antibody Detection Kit is a rapid immunochromatographic assay. intended for the qualitative detection of antibodies against *Helicobacter pylori* (*H. pylori*) in urine to aid in the diagnosis of *H. pylori* infection. The RAPIRUN Kit is suitable for use in both point-of-care and clinical laboratory settings.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K052716